REMARKS

Applicants thank the Examiner for the very thorough consideration given the present application.

Claims 1, 4-16, 23-28 and 36-42 are pending in this application. Claims 1 and 23 are independent.

By this amendment, claims 1, 4-6, 9-16, 23-26 and 28 are amended, claims 2-3, 17-22 and 29-35 are canceled without prejudice, and claims 36-42 are added. No new matter is involved.

Reconsideration of this application, as amended, is respectfully requested.

Priority Under 35 U.S.C. § 119

Applicants thank the Examiner for acknowledging Applicants' claim for foreign priority under 35 U.S.C. § 119, and receipt of the certified priority document.

Information Disclosure Citation

Applicants thank the Examiner for considering the reference(s) supplied with the Information Disclosure Statements (IDSs) filed on June 22, 2006 and July 10, 2010, and for providing Applicants with an initialed copy of the PTO/SB/08 form filed with the IDS filed on July 10, 2010 and for listing the non-patent literature document set forth in the IDS filed on June 22, 2006 on the Form PTO-892 attached to this Office Action..

Claim Objection

Claim 35 is objected to for including extraneous language. Applicants thank the examiner for pointing out this issue. This objection is respectfully traversed as moot because claim 35 has been canceled without prejudice.

Claim Rejections under 35 USC §112, Second Paragraph

Claims 4, 5, 11, 18, 19, 24, 25, 30, 31, 34 and 35 stand rejected under 35 USC §112, second paragraph, for being vague and indefinite. This rejection is respectfully traversed. It is traversed as moot regarding claims 18, 19, 30, 31, 34 and 35, which have been canceled without prejudice.

The rejection regarding 4, 5, 11, 24 and 25 is traversed based on the amendments to those claims to remove the "preferably" and/or "typically" language, and the associated values.

Reconsideration and withdrawal of this rejection are respectfully requested

Rejection Under 35 U.S.C. § 102

Claims 17 and 33 stand rejected under 35 U.S.C. § 102(b) as being anticipated by EP 217771 to Johansson et al. ("Johansson"). This rejection is respectfully traversed.

The present invention generally relates to a catheter assembly comprising a wetting fluid for wetting of a hydrophilic surface layer on a catheter, the wetting fluid comprising at least one dissolved osmolality-increasing compound and wherein the total concentration of the dissolved osmolality-increasing compound(s) exceeds 600 mOsm/dm^3.

In Johansson, the osmolality increasing compound on the catheters was integrated into the hydrophilic coating of the catheters, and not dissolved in the wetting liquid. Thus, in the catheters discussed in Johansson, the osmolality increasing compound is provided in the dry coating of the catheters, and consequently the coatings have a high concentration of osmolality increasing compound even before being wetted with the wetting liquid during the activation phase. However, the wetting fluid in itself does not comprise any osmolality increasing compound.

Thus, Johansson differs from the present invention, which is concerned with a fundamentally different way of providing the osmolality increasing compound to the coating, namely to provide osmolality increasing compound in the wetting fluid.

Moreover, this rejection is moot because claims 17 and 33 have been canceled.

Accordingly, reconsideration and withdrawal of this rejection of claims 17 and 33 are respectfully requested

Rejections under 35 U.S.C. § 103

Claims 1, 3-6, 16, 18-20, 24-26, 30, 31, 34 and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 97/26937 to Israelsson ("Israelsson I) in view of the Bongard non-patent literature reference ("Bongard").

Claims 1, 2, 7-15, 21-23, 27-29 and 32 stand rejected under3 35 USC §103(a) as being unpatentable over WO 00/47494 to Israelsson ("Israelsson II) in view of the Bongard non-patent literature reference ("Bongard").

These rejections are respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

Because the rejection is based on 35 U.S.C. § 103, what is in issue in such a rejection is "the invention as a whole," not just a few features of the claimed invention. Under 35 U.S.C. § 103, "[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The determination under § 103 is whether the claimed invention *as a whole* would have been obvious to a person of ordinary skill in the art at the time the invention was made. *See In re O'Farrell*, 853 F.2d 894, 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety. *See Medtronic, Inc. v. Cardiac Pacemakers. Inc.*, 721 F.2d 1563, 1567, 220 USPQ 97, 101 (Fed. Cir. 1983).

In rejecting claims under 35 U.S.C. § 103, it is incumbent on the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In doing so, the Examiner is expected to make the factual determinations set forth in *Graham v John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), and to provide a reason why one of ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. *See Uniroyal*

Inc. v. F-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 825 (1988); *Ashland Oil, Inc. v Delta Resins & Refactories, Inc.*, 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986); *ACS Hospital Systems, Inc. v Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of presenting a *prima facie* case of obviousness. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *See In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783 84 (Fed. Cir. 1992). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be suggested or taught by the prior art. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1970). All words in a claim must be considered in judging the patentability of that claim against the prior art. *See In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

A suggestion, teaching, or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." *See C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." *See In re Dembiczak*, 175 F.3d 994 at 1000, 50 USPQ2d 1614 at 1617 (Fed. Cir. 1999).

Moreover, it is well settled that the Office must provide objective evidence of the basis used in a prior art rejection. A factual inquiry whether to modify a reference must be based on objective evidence of record, not merely conclusory statements of the Examiner. *See In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

Furthermore, during patent examination, the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785788 (Fed. Cir. 1984). If the PTO fails to meet this burden, then the Applicants are entitled to the patent. Only when a

prima facie case is made, the burden shifts to the Applicants to come forward to rebut such a case.

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness:" *In re Kahn*, 441 F.3d 977,988(Fed. Cir. 2006) (quoted with approval in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

In the sentence just prior to citing the *Kahn* case, the U.S. Supreme Court clearly stated that there has to be an apparent reason to combine the known elements in the manner claimed. The Office has the burden of making out a *prima facie* case of obviousness, i.e., by presenting objective factual evidence of a reason to combine the known elements in the manner claimed. The *KSR* decision did not lift that burden from the Office.

The articulated reasoning has to express a rationale explaining what would have led an ordinarily skilled artisan to combine selected features from each reference in a way that would have resulted in the claimed invention. See, *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). Thus, the Supreme Court reaffirmed the fundamental principles set forth in the *Graham v. John Deere Co.* decision, cited and discussed above. Moreover, as noted in *In re Ravi Vaidanathan,* Appeal No. 2009-1401, Opinion dated May 19, 2010, (Fed, Cir. 2010), the Federal Circuit stated the following:

> Obviousness is determined as a matter of foresight, not hindsight. *See id.* at 421 (citing *Graham*, 383 U.S. at 36). *KSR* did not free the PTO's examination process from explaining its reasoning. In making an obviousness rejection, the Examiner should not rely on conclusory statements that a particular feature of the invention would have been obvious or was well known. Instead, the Examiner should elaborate, discussing the evidence or reasoning that leads the Examiner to such a conclusion. Generally, the Examiner cites prior art references to demonstrate the state of knowledge. *See* 37 C.F.R. § 1.104(c)(2) ("In rejecting claims for want of novelty or obviousness, the Examiner must cite the best references at his or her command."); Manual of Patent Examining Procedure (MPEP) § 706.02 (8th ed., rev. July 2008) ("Prior art rejections should ordinarily be confined strictly to the best available art. [citing exceptions] Such rejections should be backed up by the best other art rejections available."). If it is not possible for the Examiner to provide this type of information, the Examiner might choose instead to provide an affidavit detailing the Examiner's own personal knowledge (as a person

> approximating one of ordinary skill in the art) of the technology in question. *See* 37 C.F.R. § 1.104(d)(2) ("When a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the Applicant, by the affidavit of such employee, and such affidavit shall be subject to contradiction or explanation by the affidavits of the Applicant and other persons."). Where, as here, prior art references are cited to support an obviousness rejection, the references themselves need not in every case provide a "specific hint or suggestion" of the alteration needed to arrive at the claimed invention; the Examiner's analysis "may include recourse to logic, judgment, and common sense available to a person of ordinary skill that do not necessarily re-quire explication in any reference or expert opinion." *Perfect Web Techs. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009). In these cases the Examiner should at least explain the logic or common sense that leads the Examiner to believe the claim would have been obvious. Anything less than this results in a record that is insulated from meaningful appellate review. *Zurko*, 258 F.3d at 1386. If the examiner is able to render a claim obvious simply by saying it is so, neither the Board nor this court is capable of reviewing that determination. *See KSR*, 550 U.S. at 418, citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").

The two independent claims, as amended, recite an assembly in which the wetting fluid is stored separately.

The presently claimed invention provides a catheter assembly for hydrophilic urinary catheters, where the hydrophilic coatings have an improved stability during wetting (i.e. the resulting osmolality in the coating when wetted is less dependent on the wetting time) and exhibit lower friction (i.e. a lower extraction force is required) and improved water retention (i.e. an increase in the remaining wetting fluid content of the catheters after drying) than would have been expected *a priori*.

Seen from the perspective of the user, who is typically a disabled person confined to a wheel chair, initial friction has the positive consequence that insertion and withdrawal of the catheter is relatively easy and painless. Further, the high water retention (i.e. long drying time) has the consequence that a longer period is available for the user, both in terms of the handling time before insertion and the available time before it potentially becomes painful to remove the catheter after insertion. It should further be mentioned that catheters have a tendency to dry out

at the insertion point (i.e. the boundary between free air and the urethra) and this may cause considerable pain when removing a catheter because it adheres to the mucous membrane at the urethral opening. Still further, the increased stability during wetting makes the wetting process less critical, and reduces problems related to a too short or a too long wetting period.

Altogether, the technical advantages obtained (low friction, long-time water retention and stability during wetting) provides for a catheter assembly which is more user friendly because it is easy to activate before use, easy to insert, permits a longer time for handling and does not have to be removed within a very short time after insertion. This also means that the technical advantages are highly relevant in the real-life situation where the catheter is used.

Thus, the objective of the present invention may be seen as the quest for a more user friendly urinary catheter assembly, and more specifically an assembly that solves three equally important technical problems: to provide a catheter assembly that 1) maintain/obtain reduced friction of the hydrophilic coating of the catheter, 2) have an improved stability during wetting and 3) maintains a wetted state (conserves slipperiness) for a prolonged period of time.

The solution provided by the present invention is to provide a wetting fluid for wetting of a hydrophilic surface layer on a catheter comprising a total concentration of at least one dissolved osmolality-increasing compound(s) exceeding 600 mOsm/dm^3.

Applicants respectfully submit that, based on the teachings of the prior art, this solution is far from obvious to one having ordinary skill in the art.

Because the patent reports and acknowledges the advantages of both prolonged wetted state AND the advantages of a reduced friction AND the increased stability during wetting, the skilled person would not combine Bongard with Israelsson 1/Israelsson 2 in order to arrive at the claimed subject matter because neither Bongard nor Israelsson 1 / Israelsson 2 points to anything remotely like the surprising findings of Tables 1-3 of the present application.

In table 1 of the present application, a comparative experiment is discussed related to the importance of the concentration of the osmolality-increasing compound in the wetting liquid for the resulting friction of the catheter surface when wetted. As is clearly evident from the measurements illustrated in table 1, there is a dramatic improvement and decrease in the required extraction force when wetting fluids having an osmolality level of 700 mOsm/dm^3 or above is

used, compared to when a level of 500 mOsm/dm^3 is used. This effect is clearly visible in both the catheter types used for the experiment.

By the present inventors, it has been found that an omsolality level of 600 mOsm/dm^3 or above leads to a dramatic improvement in terms of the friction on the catheter surface (as discussed in relation to Table 1 in the application).

However, it is respectfully submitted that such a result is far from obvious in view also of Johansson, since it would not have been obvious what the resulting concentration of osmolality increasing compound in the wetted catheter coating would have been when using a certain osmolality level in the wetting fluid. Further, it would not have been obvious for the skilled addressee how long it would take (seconds, hours, weeks ...) to reach a certain concentration of osmolality increasing compound in the wetted catheter coating when a certain osmolality level in the wetting fluid was used. Thus, the skilled addressee would at the time, and based on the teachings from the cited art, not be able to foresee the resulting effect on the catheter coatings by using a wetting liquid with a certain osmolality level.

In table 2 of the present application, a comparative experiment is discussed related to the stability of the wetting process for a catheter where the osmolality increasing compound is integrated in the coating compared to a catheter where the osmolality increasing compound is dissolved in the wetting liquid. As is clearly evident from the measurements illustrated in table 2, there is a dramatic improvement in stability in the catheter 2 in which the osmolality increasing compound is dissolved in the wetting fluid, compared to catheter 1 in which the osmolality increasing compound is incorporated in the hydrophilic coating.

In table 3 of the present application, a comparative experiment is discussed related to the water retention (wetting fluid content after drying) of a catheter where the osmolality increasing compound is integrated in the coating compared to a catheter where the osmolality increasing compound is dissolved in the wetting liquid. As is clearly evident from the measurements illustrated in table 3, the wetting fluid content in the catheters 2 are significantly higher than in the catheters 1, and the water retention in the catheters wetted by a wetting fluid in which the osmolality increasing compound is dissolved is apparently improved over the water retention in

the catheters having a corresponding concentration of osmolality increasing compound in the coating.

Additionally, Applicants respectfully submit that the aforementioned tables in their Application present a detailed factual basis on which to conclude that the claimed invention has achieved unexpected results.

The primary references used on these two rejections are Israelsson I and Israelsson II.

Regarding Israelsson 1, Applicants respectfully note that even though it discloses a catheter assembly structurally similar to the presently claimed invention, and also mentions the possibility of using saline as a wetting fluid, it does not disclose including an osmolality increasing compound at the very high level of such a compound as positively recited in the claims. Moreover, Israelsson fails to disclose any specific advantages or reasons for using such a high concentration.

Applicants respectfully submit that the mentioning of "saline" in Israelsson 1 is clearly directed to normal saline and not hypertonic saline.

Regarding Israelsson 2, Applicants respectfully note that Israelsson II differs from the claimed invention in the same respect as does Israelsson I, as discussed in the previous paragraph, and further differs from the claimed invention in that Israelsson 2 discloses a catheter assembly where the catheter is maintained in direct contact with the wetting fluid instead of being stored separately prior to being used.

Using Israelsson 1 as a starting point, an objective technical problem may be seen as providing a catheter assembly which in the use situation has a very high osmolality, and which provides a lowered sensibility to variations in wetting time, and which maintains a wetted state (conserves slipperiness) for a longer period of time. There is no guidance in respect of this problem in any of the cited prior art documents.

Israelsson 2 is related to a different type of catheter product, not at all affected by variations on wetting time, since it is maintained wetted during a very long time. Further, it is noted that Israelsson 2 does not disclose any specific concentration of the osmolality-increasing agent to be used, or even that such a concentration is of any significance in respect of the properties of the catheter. Further, Johansson is directed to provision of an osmolality increasing

agent in a different way (in the dry catheter), and also at lower concentrations. Still further, Bongard is directed to hypertonic saline, to be used for totally different purposes.

In an attempt to remedy the shortcomings of Israelsson I and Israelsson II, the outstanding Office Action turns to Bongard. Bongard discusses so-called "hypertonic saline". By way of background, Applicants respectfully submit that one of ordinary skill in the art understands that normal saline is a solution of 0.90% w/v of NaCl, about 300 mOsm/L. Such normal saline may also be referred to as *physiological saline* or *isotonic saline*. Hypertonic saline may be used in perioperative fluid management protocols to reduce excessive intravenous fluid infusions and lessen pulmonary complications. Hypertonic saline is used in treating hyponatremia. However, rapid correction of hyponatremia via hypertonic saline, or via any saline infusion > 40 mmol/L (Na+ having a valence of 1, 40 mmol/L = 40 mEq/L) greatly increases risk of central pontine myelinolysis (CPM), and so requires constant monitoring of patient response. Moreover, due to hypertonicity, administration may result in phlebitis and tissue necrosis. As such, concentrations greater than 3% NaCl should normally be administered via a central venous catheter, also known as a 'central line'. (see e.g. wikipedia: http://en.wikipedia.org/wiki/Saline_(medicine)).

Hyponatremia (Brit. Hyponatraemia) is an electrolyte disturbance in which the sodium concentration in the serum is lower than normal. In the vast majority of cases, hyponatremia occurs as a result of excess body water diluting the serum sodium and is not due to sodium deficiency. Hyponatremia is most often a complication of other medical illnesses in which excess water accumulates in the body at a higher rate than can be excreted (for example in congestive heart failure, syndrome of inappropriate antidiuretic hormone, SIADH, or polydipsia). (See e.g. wikipedia: http://en.wikipedia.org/wiki/Hyponatremia).

Thus, hypertonic saline is only used very rarely, for treatment of special illness conditions, and in particular hyponatremia, and under strong supervision. Applicants respectfully submit that this is also made clear from Bongard.

Applicants respectfully submit that none of the applied art contains a disclosure of this hypertonic saline as a wetting solution for a hydrophobic urinary catheter, and that one of ordinary skill in the art only has an appreciation of using hypertonic saline to treat special illness

conditions, and in particular hyponatremia, and only under strong supervision. Thus, there is no reasonable basis in the applied art which would provide a proper incentive to one of ordinary skill in the art to arrive at, suggest, or otherwise render obvious the claimed invention.

In Israelsson 1, the concentration of the osmolality increasing compound is not specified, and it may be assumed that the concentration is relatively low, e.g. the same as in a physiological saline solution, which is significantly lower than 600 mOsm/dm^3. It is submitted that Israelsson 1 does not disclose any specific concentration of the osmolality-increasing agent to be used, or even that such a concentration is of any significance in respect of the properties of the catheter.

Another way of addressing the shortcomings of this rejection is to note that the present invention provides a catheter assembly for hydrophilic urinary catheters, where the hydrophilic coatings have an improved stability during wetting (i.e. the resulting osmolality in the coating when wetted is less dependent on the wetting time) and exhibit lower friction (i.e. a lower extraction force is required) and improved water retention (i.e. an increase in the remaining wetting fluid content of the catheters after drying) than would have been expected *a priori*.

Seen from the perspective of the user, who is typically a disabled person confined to a wheel chair, initial friction has the positive consequence that insertion and withdrawal of the catheter is relatively easy and painless. Further, the high water retention (i.e. long drying time) has the consequence that a longer period is available for the user, both in terms of the handling time before insertion and the available time before it potentially becomes painful to remove the catheter after insertion. It should further be mentioned that catheters have a tendency to dry out at the insertion point (i.e. the boundary between free air and the urethra) and this may cause considerable pain when removing a catheter because it adheres to the mucous membrane at the urethral opening. Still further, the increased stability during wetting makes the wetting process less critical, and reduces problems related to a too short or a too long wetting period.

Altogether, the technical advantages obtained (low friction, long-time water retention and stability during wetting) provides for a catheter assembly which is more user friendly because it is easy to activate before use, easy to insert, permits a longer time for handling and does not have to be removed within a very short time after insertion. This also means that the technical advantages are highly relevant in the real-life situation where the catheter is used.

Thus, the objective of the present invention may be seen as the quest for a more user friendly urinary catheter assembly, and more specifically an assembly that solves three equally important technical problems: to provide a catheter assembly that 1) maintain/obtain reduced friction of the hydrophilic coating of the catheter, 2) have an improved stability during wetting and 3) maintains a wetted state (conserves slipperiness) for a prolonged period of time.

The solution provided by the present invention is to provide a wetting fluid for wetting of a hydrophilic surface layer on a catheter comprising a total concentration of at least one dissolved osmolality-increasing compound(s) exceeding 600 mOsm/dm^3. In view of the teachings of the prior art, this solution is far from obvious to the skilled person.

One having ordinary skill in the art would not combine Bongard with Israelsson 1/Israelsson 2 in order to arrive at the claimed subject matter because neither Bongard nor Israelsson 1 / Israelsson 2 points to anything remotely like the aforementioned surprising findings of Tables 1-3 of the present application which disclose the advantages of both prolonged wetted state AND the advantages of a reduced friction AND the increased stability during wetting.

There is nothing in the cited prior art that points in the direction of the findings of the present invention, namely that advantages in terms of both prolonged wetted state and reduced friction and stability during wetting can be obtained when adding a water soluble compound of a certain concentration to the wetting liquid for a hydrophilic coated catheter. As shown above, surprisingly the use of a wetting liquid with a concentration of dissolved osmolality increasing compound(s) exceeding 600 mOsm/dm^3 leads to a catheter assembly that is superior to the comparative examples. This unexpected result could not be predicted and is neither taught nor suggested by any of the cited references.

Furthermore, regarding Israelsson 2, it is also noted that this document discloses a catheter assembly where the catheter is constantly maintained in direct contact with the wetting fluid – i.e. the catheter is always maintained in an activated state. On the contrary, the present invention, as defined in the now submitted claims, is directed to a catheter assembly where the wetting fluid is initially kept separate from the hydrophilic surface of the catheter, and brought in contact with this only during an activation step immediately prior to use.

Thus, Israelsson 2 and the present invention, as now defined, relate to two distinctly different types of catheter assemblies.

It has been realized by the inventors that a very high level of osmolality is very advantageous for obtaining a low friction. As is demonstrated by the experiments discussed in relation to Table 1 (p. 18) there is a significant difference even when the osmolality increasing level is lowered to 500 $mOsm/m^3$ – a level which is per se considered to be a high level of osmolality, and significantly exceeding the osmolality level of e.g. physiological saline.

However, when using such high levels of osmolality, it has been found by the present inventors that wetting time significantly affects not only the resulting osmolality increasing fluid (see the experiments discussed in relation to Table 2, p. 19), but also the resulting water retention capabilities of the catheters (see the experiments discussed in relation to Table 3, p. 20).

For the foregoing reasons, Applicants respectfully submit that the Office Action fails to make out a *prima facie* case of obviousness of the claimed invention.

Thus, reconsideration and withdrawal of these two rejections under 35 USC §103(a) are respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

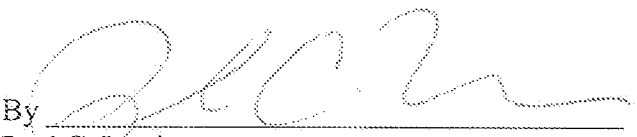
If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone Robert J. Webster, Registration No. 46, 472, at (703) 205-8000, in the Washington, D.C. area.

Prompt and favorable consideration of this Amendment is respectfully requested.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: June 14, 2011

Respectfully submitted,



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